In the United States Court of Federal Claims office of special masters

GEOFF MEAD, as parent and guardian of minor petitioner, M.M., * No. 19-667V Petitioner, * Special Master Christian J. Moran v. Filed: May 26, 2022 SECRETARY OF HEALTH AND HUMAN SERVICES, Entitlement; CIDP; diagnosis; timing Respondent.

Patricia A. Finn, Patricia Finn, P.C., Nanuet, NY, for petitioner; Kimberly S. Davey and Julia M. Collison, United States Dep't of Justice, Washington, DC, for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION¹

Geoff Mead alleges that a dose of a meningococcal vaccine his son, M.M., received on May 16, 2016, caused him to suffer a neurologic condition known as chronic inflammatory demyelinating polyneuropathy ("CIDP"). Mr. Mead presented a series of reports from doctors whom he retained. However, these reports do not persuasively establish the elements of Mr. Mead's cause of action. Most specifically, the doctors whom Mr. Mead retained have not established that CIDP is an appropriate diagnosis for M.M. Even if M.M. suffered from CIDP, Mr.

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Mead's experts have not explained how M.M. could experience the first symptoms of CIDP within one hour of the vaccination.

After these deficiencies were described in an Order to Show Cause, Mr. Mead was given a chance to respond. But, Mr. Mead has not carried his burden to present even a minimally competent case. Accordingly, Mr. Mead's case is dismissed.

I. Health and Events in M.M.'s Life

A. Events Through July 2016

M.M. was born in 2004. His health for the first 12 years of his life appears not to contribute to any neurological problems. He was regularly seen by doctors for eczema. See exhibits 18A and 18B. He participated in sports.

M.M. attended a routine health visit with his pediatrician on May 16, 2016. Exhibit 4 at 1. The pediatrician, Salvatore Caravella, indicated that his exam was normal. <u>Id.</u> at 3-4. During this visit, M.M. received a dose of the meningococcal vaccine that allegedly harmed him. Exhibit 1. The brand of the meningococcal vaccine is Trumenba.

According to Mr. Mead, within an hour of the vaccination, M.M. started to develop a fever, followed by lethargy and numbness. Pet., filed May 6, 2019, at ¶ 4; see also exhibit 2 (Mr. Mead's affidavit, dated Apr. 6, 2019) at ¶ 7. The day after vaccination, M.M. returned to the office of his pediatrician where Dr. Eve Meltzer attended to him. M.M. had a fever of 100.2 degrees. Dr. Meltzer recorded that he had a "tingly sensation over [his] body, achiness and a feeling of weakness where he felt it was difficult to grip his pencil in school." Exhibit 1 at 2. Dr. Meltzer's neurologic exam was normal. Id. Dr. Meltzer opined that M.M. was "having a reaction to the [Trumenba] vaccine which should last no more tha[n] 24-36 hours." Id. She advised the family to follow up if symptoms persisted or worsened. Id.

On May 19, 2016, M.M.'s family brought him to the emergency room at Huntington Hospital. The chief complaint was stiff neck and paresthesia. Exhibit 14 at 111 (call log).

When a doctor in the emergency room (Dr. Kashefsky) saw M.M., the doctor reported that M.M. was found "to not be in distress playing a game on his telephone and freely moving his head and neck." <u>Id.</u> Dr. Kashefsky spoke with Dr. Caravella and told Dr. Caravella about parental fears of Guillain-Barré syndrome ("GBS") post-vaccination. Dr. Caravella referred the family to a neurologist, Dr. Greg Rosenn.

Dr. Rosenn also saw M.M. on May 19, 2016. The family informed Dr. Rosenn that shortly after receiving the meningococcal vaccine, M.M. developed a fever and began complaining of weakness, headache, and numbness and tingling in his hands, feet, and lower extremities. Exhibit 14 at 105. Dr. Rosenn's neurologic exam was "non-focal." <u>Id.</u> at 106. His impression was "reaction to vaccine meningococcal (5/16)." <u>Id.</u> Dr. Rosenn also planned to "rule out polyneuropathy." <u>Id.</u> On May 20, 2016, Dr. Rosenn told Dr. Meltzer that he saw M.M. "yesterday and today with a completely normal neurologic exam and no deficits at all." <u>Id.</u> at 112 (call log).

Dr. Rosenn ordered tests for M.M. An EEG produced normal results. Exhibit 3 at 4 (May 21, 2016). Similarly, an MRI of M.M.'s brain was normal. <u>Id.</u> at 5-6 (May 22, 2016).

Dr. Rosenn reviewed these results as part of an appointment on May 31, 2016. M.M. told Dr. Rosenn that his symptoms had improved, and he did not have headaches any longer. Although his dizziness continued, it had decreased. M.M. also reported that the numbness was intermittent and limited to certain locations. Exhibit 3 at 3. Dr. Rosenn's neurologic exam was normal. Dr. Rosenn assessed M.M. as having "possible polyneuropathy but no objective findings," "possible post viral general malaise resolving," and "headaches resolved." <u>Id.</u> Dr. Rosenn also "cleared [M.M.] to go back to gym and sports." <u>Id.</u>

Nearly one month later, on June 23, 2016, M.M. returned to Dr. Rosenn. M.M. reported that his symptoms had "slowly resolved" over the past 3-4 weeks. Exhibit 14 at 108.

Most of Dr. Rosenn's neurologic exam was normal. The exceptions were that M.M. had difficulty performing "sequential finger thumb opposition" and heel and toe walking provoked "slight dizziness." Exhibit 3 at 1; exhibit 14 at 109. Dr. Rosenn's impression resembled his previous impressions. Dr. Rosenn stated that

M.M. had "1. Reaction to vaccine meningococcal (5/16) 2. Mild polyneuropathy 3. Post viral malaise." Dr. Rosenn added the symptoms have resolved. Because the symptoms had resolved, M.M. could return to his usual physical activities without any restrictions and M.M. did not need to follow up. Exhibit 3 at 2; exhibit 14 at 110.

B. Medical Records from July 2016 Through April 2017

M.M. returned to the doctor whom he was seeing for allergies, Amy Korobow, on September 11, 2016. One complaint was a "severe reaction to the Trumenba vaccine," including "weakness and fatigue." Exhibit 18A at 31. M.M.'s mother stated that his symptoms of atopic dermatitis had worsened after he stopped his allergy injections and requested resuming those injections as soon as possible. <u>Id.</u> Dr. Korobow's review of M.M.'s neurologic system was negative. <u>Id.</u> at 32.

M.M. saw two doctors on November 9, 2016. First, he saw his pediatrician and reported a sore throat. Exhibit 14 at 115.

Also, M.M. returned to Dr. Rosenn. The history included "headaches, dizziness and sensory disturbance possibly related to pneumococcal vaccine." Exhibit 3 at 7.² Dr. Rosenn noted that M.M. had chronic headaches and was previously diagnosed with polyneuropathy. <u>Id.</u>³ In conjunction with this visit, Dr. Rosenn wrote a "To Whom It May Concern" letter, stating M.M. was neurologically cleared to receive allergy shots and the flu vaccine. <u>Id.</u> at 8.

Complaining about eczema and a sore throat, M.M. saw Dr. Meltzer on December 9, 2016. Exhibit 1 at 4. Dr. Meltzer described him as having "a full body reaction to the environment." Exhibit 14 at 120. She prescribed oral steroids and creams for his eczema. <u>Id.</u> at 122. This visit did not memorialize any neurologic problems.

² The reference to "pneumococcal vaccine" appears to be an error as M.M. received a meningococcal vaccine.

³ Reading Dr. Rosenn's handwritten notes was sometimes difficult.

M.M. had appointments with his allergist, Dr. Korobow, on February 6, 2017 and April 26, 2017. In the earlier appointment, Dr. Korobow recorded that M.M. was "much better and seem[ed] to have recovered from the neurologic reaction he had to the new meningitis vaccine and he [was] still being monitored by neurology." Exhibit 18A at 28. In the latter appointment, M.M. reported an exacerbation of his eczema and swollen eyes after stopping allergy injections. Id. at 25. Dr. Korobow noted that M.M.'s eczema was "out of control." Id. at 27. She recommended consulting M.M.'s neurologist as to whether M.M. could participate in immunotherapy. Dr. Korobow also prescribed oral steroids. Id.

Interspersed with the appointments with Dr. Korobow, M.M. also saw Dr. Rosenn. On December 12, 2016, M.M. complained to Dr. Rosenn about headaches that were "constant [and] daily." Exhibit 3 at 12. Other complaints included dizziness and sensory disturbance. Dr. Rosenn's neurologic exam was normal. Id.

Follow-up appointments with Dr. Rosenn occurred on February 1, 2017 and March 1, 2017. Exhibit 3 at 10-11. The neurologic exams in both appointments were normal. <u>Id.</u>

C. Medical Records from May 2017 Through September 2017

M.M. reported experiencing numbness from his legs to his chest at a visit to the emergency room at Huntington Hospital on May 30, 2017. Exhibit 6 at 2. The history of his present illness included "presumed mild GBS approximately 1 year ago after a meningitis vaccine." <u>Id.</u> at 8. An exam indicated weakness in all four extremities. <u>Id.</u> at 10. He was then transferred to another facility. <u>Id.</u> at 13.

At the second hospital (Cohen Children's Medical Center / Northwell Health), M.M. again presented with "upper extremity and lower extremity weakness and numbness extending to the waist." Exhibit 5 at 3. The previous medical history likewise states that M.M. had "migraines and history of Guillain Barre syndrome-like episode after meningitis vaccine in the fall." <u>Id.</u> An exam revealed that M.M. had normal reflexes. His sensation to light touch was decreased on both his arms and legs. <u>Id.</u> at 4. M.M. was discharged with a plan to obtain a nerve conduction study ("NCS"). Id.

Dr. Rosenn telephoned Huntington Village Pediatrics to inform Dr. Caravella that M.M. had been seen in two facilities "due to proximal muscle weakness, sensory disturbance [on the] arms and legs and around [the] waist." Exhibit 14 at 137 (May 31, 2017). Dr. Rosenn said that "last year [P.M.] had a 'strange' reaction to Meningitis B vaccine with neuro[logical] [signs and symptoms] but these resolved." <u>Id.</u> Dr. Rosenn wondered "if there is a relationship or if some neuro[logical] issue actually existed that is now emerging again." <u>Id.</u>

Following M.M.'s trips to the hospital, Dr. Rosenn saw M.M. on June 1, 2017. M.M. stated that he had a tingling sensation in his legs that spread to his arms and felt "weak and off balance." Exhibit 3 at 20. The neurologic exam was essentially normal. <u>Id.</u> at 21. To rule out peripheral nerve dysfunction, Dr. Rosenn recommended an electromyography ("EMG") / NCS. <u>Id.</u> at 22. A note from July 14, 2017 indicates that M.M. did not receive this testing because the family could not find a provider. Exhibit 14 at 143 (Dr. Caravella).

At a follow-up visit with Dr. Rosenn on June 21, 2017, M.M. reported that his numbness and weakness had lessened, and he was having headaches less frequently. <u>Id.</u> at 19.

During a well visit at Huntington Village Pediatrics, M.M. and his mother stated that M.M. was still having "ongoing neurological issues since receiving [the] [T]rumenba vaccine last year," including a "numbness/burning sensation," "extreme pain to torso when shower[ing]," and "weakness in both legs when he stands too long." Exhibit 14 at 142 (July 14, 2017). The neurologic exam by Dr. Caravella was normal. <u>Id.</u> at 146. Dr. Caravella's impressions included: "extreme exercise intolerance: related to neurological situation post vaccination or ??beginning of an emotional component to this illness." <u>Id.</u> at 148.

Dr. Caravella's July 14, 2017 record reflects some concern about a possible vaccine-induced injury. Dr. Caravella wrote:

Vaccine reaction: unclear but it would seem that based on timeline possible [sic]. Flu like [signs and symptoms including] fever [and] headache day after vaccination, sub[sequently] seen by Dr. Rosen[n], exacerbation of symptoms months later, month after child went to

Princeton for a sports tournament, child is known allergic seasonal, foods, etc, has eczema, asthma [-] is this all immunological? Auto immune? I suggested to the father that if SB neuro was not helpful that we should consider NYC [Presbyterian] or Boston Children's. Get evaluations from neurology, allergy/immunology and rheumatology.

Exhibit 14 at 149.

After Dr. Caravella referred M.M. to a dermatologist, M.M. saw Dr. Leonard Kristal on July 25, 2017. Exhibit 14 at 155. Dr. Kristal told Dr. Caravella that M.M.'s "burning skin, severe peeling, [and] paresthesia [we]re all likely related to the extreme eczema . . . and that the present treatments [we]re not addressing the acute nature of the problem." <u>Id.</u> at 154 (call log). Dr. Kristal stated that an autoimmune condition was not likely.

D. Medical Records from October 2017 Through December 2017

M.M. saw Dr. Korobow on October 6, 2017. Exhibit 18A at 22. Dr. Korobow recorded that M.M. "was really under excellent control while on immunotherapy but his eczema has flared and is worse than ever since a few months after stopping treatment." <u>Id.</u> Dr. Korabow added that "[t]herapy was stopped because he had an idiopathic neurologic reaction to [Trumenba] and he has been suffering with severe headaches since that time." <u>Id.</u> Dr. Korobow planned to start immunotherapy. <u>Id.</u> at 24.

M.M. had his first appointment with Dr. Lourdes Bello-Espinosa, a neurologist, on October 18, 2017. M.M.'s parents informed Dr. Bello-Espinosa that M.M. developed numbness and tingling in his hands and feet and lower extremities shortly after a dose of the meningococcal vaccine in May 2016. Exhibit 10 at 3. They also told her that M.M. "has never been symptom free and he had an exacerbation of his symptoms approximately 1 year after . . . in May of 2017 in the setting of a viral infection." <u>Id.</u> Dr. Bello-Espinosa's review of systems indicated numbness and tingling in M.M.'s extremities. <u>Id.</u> at 4. However, her neurologic exam, including a test of his reflexes and strength, was normal. Id. at 6-7. Dr. Bello-Espinosa's impression included "headaches,"

neuropathy and post vaccination reaction." <u>Id.</u> at 7. She recommended electrodiagnostic testing.

M.M. underwent an EMG / nerve conduction velocity ("NCV") study on November 20, 2017. Exhibit 8 at 1. The doctor who conducted the test, Michael Guido, stated, "This is a normal study. There is no unequivocal evidence of neuropathy at this time." <u>Id.</u> at 3.

Dr. Bello-Espinosa reviewed these results in a follow-up appointment on December 13, 2017. She stated the nerve conduction study "showed decreased amplitude of potential, likely indicative of recovery from his prior injury." Exhibit 9 at 18. Her neurologic exam was normal. <u>Id.</u> at 22.

E. Other Neurologic Records Created in 2018 and 2019⁴

In 2018, M.M. saw Dr. Bello-Espinosa twice. On each occasion, the purpose of the visit was a follow-up for a vaccine reaction. Exhibit 9 at 8 (June 6, 2018); exhibit 21 at 91 (Oct. 15, 2018). On both occasions, his neurologic exam was normal. Exhibit 9 at 11-12; exhibit 21 at 94.

Two more appointments with Dr. Bello-Espinosa happened in 2019. On February 4, 2019, M.M.'s mother asked whether M.M. could stop taking medications, but Dr. Bello-Espinosa wanted a follow-up EMG / NCV before tapering any medications. Exhibit 14 at 214. A follow-up visit was on July 29, 2019, during which M.M. was doing well. <u>Id.</u> at 222.

II. Procedural History

Mr. Mead alleged that the meningococcal vaccine caused his son, M.M., to suffer chronic inflammatory demyelinating polyneuropathy. Pet., filed May 6, 2019. Mr. Mead periodically filed medical records and other material.

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⁴ This section omits a discussion of records from M.M.'s allergist and pediatricians.

Respondent opposed the award of compensation. Respondent commented that M.M.'s treating doctors did not diagnose him with CIDP, despite several exams within a week of the vaccination. Resp't's Rep., filed Jan. 28, 2020.

Mr. Mead anticipated obtaining a report from an expert. Thus, the undersigned issued Instructions to guide the presentation of opinions. Order, issued Apr. 13, 2020.

Obtaining a report from an expert took a relatively long amount of time. Mr. Mead eventually submitted a report from Dr. Yehuda Shoenfeld on February 2, 2021. Exhibit 27.

As explained in a February 24, 2021 status conference, Dr. Shoenfeld's report was not persuasive. Although the petition claimed CIDP, Dr. Shoenfeld did not discuss CIDP very much. Dr. Shoenfeld did not set forth a supported theory by which the meningococcal vaccine can cause CIDP. Another significant omission was that Dr. Shoenfeld did not explain timing at all. Accordingly, Mr. Mead was directed to obtain a supplemental report from Dr. Shoenfeld. Order, issued Feb. 24, 2021.

Mr. Mead did not immediately file a report from Dr. Shoenfeld. Instead, Mr. Mead presented a report from a neurologist, Dr. Avinoam Shuper. Exhibit 55. Dr. Shuper opined that M.M. suffered from "inflammatory neuropathy which resembled GBS in the beginning but progressed to CIDP." <u>Id.</u> at 14. Thereafter, on May 18, 2021, Mr. Mead filed a one-sentence report from Dr. Shoenfeld. Exhibit 73.

A status conference was held on August 24, 2021, to discuss Mr. Mead's expert reports. The undersigned discussed with Mr. Mead's counsel that Dr. Shoenfeld did not appear to be helpful to Mr. Mead in that he did not adequately address the relevant issues outlined in the expert instructions and the previous guidance. Specifically, he appeared not to address timing. Mr. Mead's counsel requested 60 days to consult with Dr. Shoenfeld or potentially to speak with another neurologist or other expert and submit a supplemental expert report.

Mr. Mead submitted another report from Dr. Shoenfeld on October 14, 2021. Exhibit 74. This two-page report remained unpersuasive.

An Order to Show Cause was issued on October 15, 2021. This order explained that Mr. Mead had not presented a minimally competent case. Thus, Mr. Mead was allowed a final opportunity either to cure the deficiencies or to have his case dismissed.

Mr. Mead filed a five-page response to the Order to Show Cause on December 14, 2021. Mr. Mead submitted additional evidence in conjunction with this response on December 14, 2021, and on January 3, 2022. The Secretary provided comments on Mr. Mead's response on February 3, 2022. This document is 14 pages. Mr. Mead submitted a reply, which is six pages, on March 15, 2022. With this reply, Mr. Mead submitted seven additional exhibits, including another report from Dr. Shoenfeld.⁵ The case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3)

⁵ Given that the Order to Show Cause identified the critical issues in the case and the Secretary's February 3, 2022 comments about Mr. Mead's response to the Order to Show Cause did not include any new evidence, Mr. Mead's introduction of new evidence in conjunction with a reply brief is a questionable practice. Mr. Mead did not explain why any of the material submitted on March 15, 2022 could not have been submitted with his initial response to the Order to Show Cause on December 14, 2021. Nevertheless, all evidence has been considered.

a showing of a proximate temporal relationship between vaccination and injury." <u>Althen v. Sec'y of Health & Hum. Servs.</u>, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

A. Diagnosis

In <u>Broekelschen v. Secretary of Health & Human Services</u>, 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the <u>Althen</u> test." Here, Mr. Mead has not established that M.M. suffered from the condition he alleges the meningococcal vaccine caused.

The question of diagnosis has been an issue throughout the case. The petition alleges the meningococcal vaccine resulted in a "diagnosis of chronic inflammatory demyelinating polyneuropathy." Pet., filed May 6, 2019, at ¶ 23. However, the Secretary maintained that "the medical records fail to provide preponderant proof that M.M. suffers from the condition for which petitioner seeks compensation, namely CIDP." Resp't's Rep., filed Jan. 28, 2020, at 14. The Secretary elaborated:

Petitioner asserts that Dr. Bello-Espinosa's use of the diagnostic code for CIDP is evidence that M.M. suffered from that condition. However, M.M.'s records do not document an evaluation or treatment for CIDP by any of his doctors, including Dr. Bello-Espinosa. None of M.M.'s records immediately following his vaccination or even after seeing Dr. Bello-Espinosa document a diagnosis of or concern for CIDP. Additionally, the medical records reflect that M.M. never had objective evidence of polyneuropathy.

<u>Id.</u> at 14-15 (internal citations omitted). Thus, the expert instructions directed the parties to have their experts discuss diagnosis. Instructions, issued Apr. 13, 2020, at 5-6.

After that point, Mr. Mead's discussion about CIDP has been lacking. Dr. Shoenfeld's first report barely mentioned CIDP. <u>See</u> exhibit 27. Dr. Shuper's

report stated M.M.'s "disease cannot be defined as neither GBS nor CIDP alone, but is on the clinical spectrum between these 2 diseases." Exhibit 55 at 17; accord id. at 14. Thus, to some extent, Dr. Shuper undermines the allegation that M.M. suffered from CIDP. The more significant problem is that Dr. Shuper did not explain the basis for his conclusion that M.M. suffered from an "inflammatory neuropathy." For example, Dr. Shuper did not explain why his diagnosis is appropriate given that Dr. Rosenn, a neurologist, found that M.M. was neurologically normal on May 19, 2016. Exhibit 14 at 106. Dr. Shuper also did not address the normal results on EMG / NCS studies. Dr. Shuper's failure to engage with the evidence makes his opinion a conclusion without support. It, therefore, lacks persuasive value. Instead, the more valuable source is Dr. Rosenn, who did not diagnose M.M. with CIDP after examining him more than once. See Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1353-54 (Fed. Cir. 2011) (ruling that a special master was not arbitrary in rejecting a neurologic diagnosis offered by an expert retained in the litigation that a treating neurologist did not find); D'Angiolini v. Sec'y of Health & Hum. Servs., No. 99-578V, 2014 WL 1678145, at *24 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (indicating that the views of a treating doctor on diagnosis are "almost definitive"), mot. for rev. denied, 122 Fed. Cl. 86 (2015), aff'd without op., 645 F. App'x 1002 (Fed. Cir. 2016).

While Mr. Mead's failure to establish with preponderant evidence that M.M. suffers from the condition for which he seeks compensation, CIDP, could by itself justify a dismissal, Mr. Mead's case is flawed for another reason as well.

B. Timing

The "proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." <u>Bazan</u>, 539 F.3d at 1352.

The Order to Show Cause linked the theory being offered to the appropriate temporal interval.

Further, even assuming that Dr. Shoenfeld had established, more-likely-than-not, that molecular mimicry constitutes a persuasive theory that the

meningococcal vaccine can cause inflammatory neuropathy, Dr. Shoenfeld has not explained how this theory meshes with the sequence of events. The medically acceptable timeframe depends, at least in part, on the theory being offered. <u>Langland v. Sec'y of Health & Human Servs.</u>, 109 Fed. Cl. 421, 443 (2013).

Order, issued Oct. 15, 2021, at 2.

The Order to Show Cause likewise indicated that Dr. Shoenfeld had failed to explain how his molecular mimicry theory could explain how M.M. developed neurologic problems within hours after the vaccination.

Molecular mimicry is a theory that posits the immune system going through multiple steps leading to an attack on host tissues. This process takes multiple days, probably at least five days. Contreras v. Sec'y of Health & Human Servs., No. 05-626V, 2012 WL 1441315, at *9-24 (Fed. Cl. Spec. Mstr. Apr. 5, 2012) (lengthy discussion of the time for molecular mimicry), mot. for rev. denied in relevant part after intervening proceedings, 121 Fed. Cl. 230, 246-47 (2015), vacated on other grounds and remanded, 844 F.3d 1363 (Fed. Cir. 2017); Forrest v. Sec'y of Health & Human Servs., No. 14-1046V, 2019 WL 925495, at *3-8 (Fed. Cl. Spec. Mstr. Jan. 28, 2019).

But, here, Dr. Shoenfeld and Dr. Shuper assert that M.M. experienced neurologic problems within one hour of the vaccination. Exhibit 55 at 6; exhibit 74 ¶ 2. Dr. Shoenfeld has not explained how the process of molecular mimicry can lead to symptoms within one hour.

Id. at 2-3.

Mr. Mead has not filled this gap. The initial response to the Order to Show Cause did not discuss timing at all. <u>See</u> Pet'r's Resp. As the Secretary stated,

"petitioner cites nothing in support of his assertion that molecular mimicry can produce clinical symptoms within one hour, as alleged here." Resp't's Comments, filed Feb. 3, 2022, at 13.

Mr. Mead's final opportunity to submit at least a minimally competent case came as part of his reply. There, Mr. Mead maintained that Dr. Shoenfeld responded to the appropriate timeframe. Pet'r's Reply, filed Mar. 15, 2022, at 3. Actually, Dr. Shoenfeld did not. His latest report, too, did not address why an interval of just one hour is appropriate for molecular mimicry. This report does not use the terms "time," "timing," "hours," or "days." See exhibit 84.

The Federal Circuit has recognized that that the onset of an injury may occur "too soon" after a vaccination for a conclusion that the vaccine caused the injury. Bazan, 539 F.3d at 1352 (reinstating a special master's finding that an injury developing 11 hours after vaccination was not appropriate). Here, Mr. Mead's case resembles the facts in Bazan. There is no minimally competent evidence for finding that the process of molecular mimicry can produce symptoms of CIDP within a few hours. This lack of evidence means that Mr. Mead cannot receive compensation.

C. Dismissal Is Appropriate

Mr. Mead has had multiple opportunities to present a minimally persuasive case. At the end of the process that began with the Order to Show Cause, Mr. Mead has not established that M.M. suffered from CIDP. But, the more significant problem is that Mr. Mead has not explained how CIDP can develop within a few hours after a vaccination. This gap has been pointed out many times and yet remains.

Due to this gap in evidence, Mr. Mead's case is dismissed. Mr. Mead's case is not being dismissed as a sanction or a penalty. See Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642 (2021) (denying a motion for review of a decision dismissing a case for failure to prosecute despite the presence of expert reports). Mr. Mead's case is dismissed because the evidence is not sufficient to proceed.

V. Conclusion

Mr. Mead has not supported his claims with sufficient evidence for the case to proceed. Accordingly, the Clerk's Office is instructed to enter judgment in

accord with this decision unless a motion for review is filed. Information regarding the content and deadline for a motion for review is available in the Vaccine Rules posted to the Court's website.

IT IS SO ORDERED.

s/Christian J. Moran Christian J. Moran Special Master